

PATENT COOPERATION TREATY

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TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

Docket System

Status Report

Docket Book

IPRP

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ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

04 August 2005 (04.08.2005)

Applicant's or agent's file reference

DC-0248

IMPORTANT NOTICE

International application No.

PCT/US2004/001382

International filing date (day/month/year)

20 January 2004 (20.01.2004)

Priority date (day/month/year)

21 January 2003 (21.01.2003)

Applicant

TRUSTEES OF DARTMOUTH COLLEGE et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Simin Baharlou

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PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference DC-0248	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2004/001382	International filing date (<i>day/month/year</i>) 20 January 2004 (20.01.2004)	Priority date (<i>day/month/year</i>) 21 January 2003 (21.01.2003)]
International Patent Classification (IPC) or national classification and IPC A61K 31/519, C07D 487/02, C12Q 1/02		
Applicant TRUSTEES OF DARTMOUTH COLLEGE		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*. 1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 22 July 2005 (22.07.2005)
	Authorized officer Simin Baharlou Telephone No. +41 22 338 71 30

PATENT COOPERATION TREATY

REC'D 18 FEB 2005

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT MPO PCT

To:
JANE MASSEY LICATA
LICATA & TYRRELL PC
66 E. MAIN STREET
MARLTON, NJ 08053

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference

Date of mailing
(day/month/year)

FOR FURTHER ACTION

See paragraph 2 below

DC-0248

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/01382

20 January 2004 (20.01.2004)

21 January 2003 (21.01.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 31/519; C07D 487/02; C12Q 1/02 and US Cl.: 435/29; 514/265.1; 544/280

Applicant

TRUSTEES OF DARTMOUTH COLLEGE

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Jeffrey E. Russel

Telephone No. (571) 272-1600

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/01382

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/01382

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>3-7</u>	YES
	Claims <u>1 and 2</u>	NO
Inventive step (IS)	Claims <u>3-7</u>	YES
	Claims <u>1 and 2</u>	NO
Industrial applicability (IA)	Claims <u>1-7</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1 and 2 lack novelty under PCT Article 33(2) as being anticipated by Gabry et al. Gabry et al teach in vivo administration of antalarmin in a pharmaceutically acceptable vehicle comprising cremophor, ethanol, and saline. See, e.g., page 475, column 2, second full paragraph. Note that an intended use limitation such as "for increasing cytotoxic T-cell lytic activity" and "for treatment of human ovarian cancer" does not impart novelty or non-obviousness to product claims where the product is otherwise taught by the prior art.

Claims 3-7 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest measuring the level of cytotoxic T-cell lytic activity in cells or tissues which have been contacted with antalarmin, and do not teach or fairly suggest administering antalarmin to tumor-bearing animals, including patients with ovarian cancer. The prior art of record does not teach or suggest that antalarmin has any effect on cytotoxic T-cell lytic activity, on cancer in general, or on ovarian cancer specifically. While Pfizer, Inc. indicates that CRF antagonists have anticancer activity in general (see, e.g., claim 11), there is no teaching or suggestion that antalarmin specifically will act by increasing cytotoxic T-cell lytic activity or anti-tumor activity.

Claims 1-7 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry. The claimed invention would have been expected to have industrial applicability in the therapeutic treatment of tumors.